

## Message Text

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PAGE 01 STATE 005216  
ORIGIN HEW-06

INFO OCT-01 AF-08 ARA-10 EUR-12 EA-09 NEA-10 ISO-00 OES-06  
SIG-02 /064 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.DONBNNK  
APPROVED BY OES/APT/BMP: WJWALSH, III  
DHEW/OIH: BROYSTER  
ARA/EX:CJACOBINI(INFO)  
EUR/EX:JLTULL(INFO)  
AF/EX:JTIERNEY(INFO)  
EA/EX:JRCUNNINGHAM(INFO)  
NEA/EX:EGABINGTON(INFO)

-----110209Z 129918 /64

P 102245Z JAN 77

FM SECSTATE WASHDC

TO AMEMBASSY HELSINKI PRIORITY

AMEMBASSY TEL AVIV PRIORITY

AMEMBASSY BANGKOK PRIORITY

AMCONSUL CURACAO PRIORITY

AMEMBASSY PARAMARIBO PRIORITY

AMEMBASSY ATHENS PRIORITY

AMEMBASSY BRIDGETOWN PRIORITY

AMEMBASSY LUSAKA PRIORITY

AMEMBASSY AMMAN PRIORITY

AMEMBASSY JAKARTA PRIORITY

AMEMBASSY PORT OF SPAIN PRIORITY

AMEMBASSY LONDON PRIORITY

AMEMBASSY MEXICO PRIORITY

AMEMBASSY QUITO PRIORITY

AMEMBASSY LIMA PRIORITY

AMEMBASSY CARACAS PRIORITY

AMEMBASSY MADRID PRIORITY

AMEMBASSY LISBON PRIORITY

AMEMBASSY CANBERRA PRIORITY

AMCONSUL HONG KONG PRIORITY

AMEMBASSY ROME PRIORITY

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AMEMBASSY PRETORIA PRIORITY

AMEMBASSY BRUSSELS PRIORITY

AMEMBASSY STOCKHOLM PRIORITY

AMEMBASSY TOKYO PRIORITY

AMEMBASSY PARIS PRIORITY

AMEMBASSY LAGOS PRIORITY

AMEMBASSY SINGAPORE PRIORITY

AMEMBASSY WELLINGTON PRIORITY  
AMEMBASSY BERN PRIORITY

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E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, XX

SUBJECT: INVITRO DIAGNOSTIC PRODUCT, UNRELIABLE  
RESULTS (RECALL NO. T-141-6).

1. FDA ADVISES OF THE FOLLOWING PRODUCT RECALL:

PRODUCT INVOLVED: BRAIN THROMBOPLASTIN FOR INVITRO  
DIAGNOSTIC USE. PRODUCT PACKAGED IN LYOPHILIZED, MULTI-  
DOSE TYPE VIALS. EACH VIAL IS PACKAGED IN TEN UNIT  
PACKAGES. CONTENTS OF EACH VIAL SUFFICIENT FOR 25  
DETERMINATIONS. PRODUCT IS USED TO TITRATE PATIENTS  
UNDERGOING ANTICOAGULANT THERAPY.

PRODUCT IDENTIFICATION: ORTHO BRAIN THROMBOPLASTIN,  
ORTHO DIAGNOSTICS INC., RARITAN, N.J. 08869. PRODUCT IS  
IDENTIFIED WITH CATALOG NO. 3133. ONE-HUNDRED SIXTEEN  
LOTS ARE UNDER RECALL. THE LOTS BEING RECALLED ARE 1N501  
THROUGH 6P616.

MANUFACTURER: ORTHO DIAGNOSTICS INC., ARLINGTON, TEXAS.

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RECALLING FIRM: ORTHO DIAGNOSTICS INC., RARITAN, N.J.  
08869.

2. REASON FOR RECALL: FOLLOWING 4 COMPLIANTS THE FIRM  
DETERMINED THAT THE PRODUCT WAS NOT GIVING RELIABLE  
CLOTING TIME. WHEN TESTED AGAINST NORMAL PLASMA THE  
TIMES ARE PROLONGED. ALTHOUGH THE TIMES ARE NOT YET  
OUTSIDE LABEL REQUIREMENTS, THEY EXCEED THE FIRM'S INTERNAL  
SPECIFICATIONS FOR "FAST PLASMA". INVESTIGATIONS BY THE  
FIRM REVEALED A PROBLEM WITH THE LYPHOLYZERS AT THE  
ARLINGTON, TEXAS PLANT. ALL PRODUCTS MANUFACTURED IN  
THESE LYPHOLYZERS ARE BEING RECALLED. THIS INCLUDES ALL  
LOTS MANUFACTURED BETWEEN JANUARY 1975 AND JULY 1976.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES  
TO DETERMINE IF THEY HAVE RECEIVED RECALL LETTERS FROM  
FIRM DATED 28 SEPTEMBER 1976. THE FIRM IS REQUESTING  
ALL CONSIGNEES TO CONTACT THE FIRM'S CUSTOMER SERVICE  
DEPARTMENT FOR RETURN AUTHORIZATION. ANY QUESTIONS

CONSIGNEES MAY HAVE REGARDING THIS RECALL SHOULD BE  
DIRECTED TO FIRM. THE CONTACT AT FIRM IS MR. DANIEL T.  
MC KIETHAN, JR. - TELEPHONE 201-524-2406.

4. FOREIGN CONSIGNEES AS FOLLOWS;

MR. BROR FELIXSON  
THE FINNISH FAIR CORP  
P O BOX 24  
SF 05521 HELSINKI 52, FINLAND

CHEMICALS AND TECHNICALS LIMITED  
P O BOX 10  
TEL-AVIV, ISRAEL

NEW FRENCH DISPENSARY  
693-699 SIPHYA ROAD  
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BANGKOK, THAILAND

NETHERLANDS ANTILLES  
B A LEON  
P O BOX 12  
CURACAO  
NETHERLANDS ANTILLES

SURINAM  
C KERSTEN AND CO N.V.  
P O BOX 1808  
PARAMARIBO, SURINAM

CHRISTOPHER PALLIDIS  
15 ALEXANDER 3 OUTSOU ST  
ATHENS T-134, GREECE

W B HUTCHINSON AND CO LTD JOHNSON AND JOHNSON SA  
CAVANS LANE GUSTAVO FERNANDEZ  
BRIDGETOWN, BARBADOS(W INDIES) BALBUENA 2, MADRID 2  
SPAIN

NATIONAL DRUG CO  
P O BOX 202 JOHNSON AND JOHNSON LTD  
KABWE, ZAMBIA APARTADO 17  
QUELUZ, PORTUGAL

JORDAN UNIVERSITY HOSPITAL  
P O BOX 9174 ETHNOR PTY LIMITED  
AMMAN, JORDAN P O BOX 134  
NORTH RYDE NSW 2113  
P. T. JANJI UTAMA AUSTRALIA  
ETHICAL PRODUCTS DEPT

TROMPOLPAS 3509 JOHNSON AND JOHNSON  
JAKARTA, INDONESIA HONG KONG LTD

P O BOX 979

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MINISTRY OF HEALTH HONG KONG  
GOVERNMENT OF TRINIDAD AND TOBAGO  
PORT OF SPAIN, TRINIDAD CILAG CHEMIE ITALIANA  
(WEST INDIES) SPA  
CASELLA POSTAL 4387  
ORTHO PHARMACEUTICAL LTD 20100 MILANO, ITALY  
P O BOX 79  
SAUNDERTON HIGH WYCOMBE ETHNOR LAB PTY LTD  
BUCKINGHAMSHIRE WP144AJ P O BOX 273  
ENGLAND HALFWAY HOUSE 1685  
TRANSVAAL, S AFRICA  
JOHNSON AND JOHNSON DE MEXICO  
S A DE C V ORTHO PHARMACEUTICA NV  
APARTADO POSTAL 1133 ANTWERPSEBAAN 19-21  
MEXICO 1, D.F. MEXICO 2340 BEERSE, BELGIUM

JOHNSON AND JOHNSON HEMISFERICA SA CILAG CHEMIE A.B.  
P O BOX 7206 FACK S-191 07 SOLLENTUNA  
GUAYAQUIL, ECUADOR SWEDEN

JOHNSON AND JOHNSON DEL PERU JAPAN  
APARTADO 1615 SANKO JUNYAKU CO LTD  
LIMA, PERU 10-6 IWAMOT O-CHO  
1 CHOME CHIYODA-KUTMM  
JOHNSON AND JOHNSON DE VENEZUELA SA BLDG  
APARTADO 40, 349 TOKYO, 101 JAPAN  
CHACAO 106, CARACAS, VENEZUELA

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LE BRUN LABORATORIES  
5 RUE DE LUBECK 75  
PARIS 16E, FRANCE

JOHNSON AND JOHNSON NIGERIA LTD  
P O BOX 3136  
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LAGOS, NIGERIA

SINGAPORE  
JOHNSON AND JOHNSON PTE LTD  
P O BOX LOCKED BAG SERVICE NO.6  
JURONG TOWN, SINGAPORE

ETHNOR PTY LTD  
27 CROWHURST ST  
NEW MARKET  
AUCKLAND, NEW ZEALAND

CILAG CHEMIE A G  
HOCHSTRASSE 205-209  
8201 SCHAFFHAUSEN  
SWITZERLAND  
KISSINGER

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NNN

## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01-Jan-1994 12:00:00 am  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** MEDICAL EQUIPMENT, CONSUMER PROTECTION, RECALLS, FOOD & DRUG REGULATIONS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Sent Date:** 10-Jan-1977 12:00:00 am  
**Decaption Date:** 01-Jan-1960 12:00:00 am  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01-Jan-1960 12:00:00 am  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1977STATE005216  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** JRWEINROTH, M.DONBNNK  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Expiration:**  
**Film Number:** D770009-0859  
**Format:** TEL  
**From:** STATE  
**Handling Restrictions:** n/a  
**Image Path:**  
**ISecure:** 1  
**Legacy Key:** link1977/newtext/t19770165/aaaacfek.tel  
**Line Count:** 240  
**Litigation Code IDs:**  
**Litigation Codes:**  
**Litigation History:**  
**Locator:** TEXT ON-LINE, ON MICROFILM  
**Message ID:** 13e9b6db-c288-dd11-92da-001cc4696bcc  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 5  
**Previous Channel Indicators:** n/a  
**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** n/a  
**Retention:** 0  
**Review Action:** RELEASED, APPROVED  
**Review Content Flags:**  
**Review Date:** 15-Oct-2004 12:00:00 am  
**Review Event:**  
**Review Exemptions:** n/a  
**Review Media Identifier:**  
**Review Release Date:** n/a  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**SAS ID:** 3630480  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** INVITRO DIAGNOSTIC PRODUCT, UNRELIABLE RESULTS (RECALL NO. T-141-6).  
**TAGS:** OGEN, ETRD, TBIO, XX, FDA, ORTHO DIAGNOSTICS INC  
**To:** HELSINKI TEL AVIV MULTIPLE  
**Type:** TE  
**vdkgvwkey:** odb://SAS/SAS.dbo.SAS\_Docs/13e9b6db-c288-dd11-92da-001cc4696bcc  
**Review Markings:**  
Margaret P. Grafeld  
Declassified/Released  
US Department of State  
EO Systematic Review  
22 May 2009  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009